UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/621,206 | 07/15/2003 | James T. Kealey | 300622008800 | 1089 |
| 7590 03/17/2008 TED APPLE (TOWNSEND AND TOWNSEND) 379 LYTTON AVENUE PALO ALTO, CA 94301 | | | EXAMINER | |
| | | | ROBINSON, HOPE A | |
| PALO ALTO, CA 94301 | | | ART UNIT | PAPER NUMBER |
| | | | 1652 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 03/17/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | |
|--|--|---|--|--|
| | 10/621,206 | KEALEY ET AL. | | |
| Notice of Allowability | Examiner | Art Unit | | |
| | HOPE A. ROBINSON | 1652 | | |
| The MAILING DATE of this communication appe All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI of the Office or upon petition by the applicant. See 37 CFR 1.313 | (OR REMAINS) CLOSED in this ap or other appropriate communication GHTS. This application is subject t | orrespondence address plication. If not included n will be mailed in due course. THIS | | |
| 1. \square This communication is responsive to $\underline{3/4/08}$. | | | | |
| 2. The allowed claim(s) is/are <u>1,5-17 and 19-21</u> . | | | | |
| 3. ☐ Acknowledgment is made of a claim for foreign priority una a) ☐ All b) ☐ Some* c) ☐ None of the: 1. ☐ Certified copies of the priority documents have 2. ☐ Certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have International Bureau (PCT Rule 17.2(a)). * Certified copies not received: Applicant has THREE MONTHS FROM THE "MAILING DATE" onoted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. | been received. been received in Application No cuments have been received in this of this communication to file a reply | national stage application from the | | |
| 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. 5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. | | | | |
| Attachment(s) 1. ☐ Notice of References Cited (PTO-892) 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material | 5. ☐ Notice of Informal F 6. ☐ Interview Summary Paper No./Mail Da 7. ☑ Examiner's Amendi 8. ☐ Examiner's Statement 9. ☐ Other | (PTO-413), te | | |

Application/Control Number: 10/621,206 Page 2

Art Unit: 1652

SUPPLEMENTAL EXAMINER'S AMENDMENT

1. This is a Supplemental Notice of Allowability to amend claim dependency.

2. An Examiner's amendment to the record appears below. Should the changes and/or

additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the

payment of the issue fee.

3. Authorization of this Examiner's amendment was given in a telephone interview with Mr.

Ted Apple on November 7, 2007, via e-mail on November 9, 2007 and telephonically on March

4, 2008.

4. The Claims have been amended as follows:

Claim 1 (Currently Amended) A recombinant host cell that produces a polyketide using a starter

unit, wherein the recombinant host cell is derived from a native host cell by modification with an

expression vector, wherein said expression vector expresses or overexpresses an atoAD enzyme

[or a positive transcription regulator that increases the expression of the atoAD enzyme,] and

wherein increased expression of the atoAD enzyme results in increased production of the starter

unit, wherein the atoAD enzyme is an acetyl-CoA acetoacetate: CoA transferase enzyme

designated EC 2.8.3.8 [by the Nomenclature Committee of the International Union of

Biochemistry and Molecular Biology and having the ability to catalyze the reaction: acetyl CoA + [acetoacetateacetate] acetoacetate \(\lefta \> \) acetate + acetoacetyl CoA].

Claim 4 (Cancelled)

Claim 10 (Currently Amended) The host cell of Claim [2] 6 that is an Escherichia coli host cell.

Claim 18 (Cancelled)

Claim 19 (Cancelled)

Claim 20 (Currently Amended) A method for producing an analog of 6-deoxyerythronolide B (6-dEB) modified by replacement of the propionate starter unit in a host cell of Claim 1, comprising culturing the host cell under conditions wherein the analog of 6-dEB is produced, and wherein said analog is 14-desmethyl-6dEB, 15-methyl-6-dEB, 15-fluoro-6-dEB, 15-chloro-6-dEB, 15-trifluoro-6-dEB, 15-hydroxy-6-dEB, 14-desmethyl-14-fluoro-6-dEB, 14-hydroxy-6-dEB, 14-desmethyl-14-chloro-6-dEB, 14-desmethyl-14-hydroxy-6-dEB, 15-(chloromethyl)-6-dEB, 14-ethyl-6-dEB, or 15-ethyl-6-dEB.

Claim 21(New) The host cell of Claim 17, further modified to overexpress a biotin ligase enzyme.

Claim 22 (New) The host cell of Claim 21 wherein the biotin ligase enzyme is encoded by the *birA* gene.

Application/Control Number: 10/621,206 Page 4

Art Unit: 1652

EXAMINER'S COMMENTS

Withdrawn-Claim Rejection 112

- 5. Previous rejections to the claims under 35 U.S.C. 112, first paragraphs enablement and written description are <u>withdrawn</u> by virtue of the amendments made herein.
- 6. The Restriction Requirement mailed on March 17, 2006 is withdrawn.
- 7. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Conclusion

8. Claims 1, 5-17 and 19-21 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

Application/Control Number: 10/621,206 Page 5

Art Unit: 1652

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed Ph.D., can be reached at (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652